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July 27, 1988

#25

Mr. Ronald Wilson
Office of the Associate Commissioner
for Health Affairs (HFY-20)
Room 11-46
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Sensor* Model Kelvin*
500 Unipolar Pulse
Generator, and Model
K Unipolar Sensing
Lead Sensor Model
Kelvin 500 Pulse
Generator. Model K
Endocardial Lead,
Model 5000
Transceiver, and
Model 50 Lead
Tester
FDA Docket # 88E-0269

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for Patent Term Extension of U.S. Patent No. 4,543,954, issued October 1, 1985. The application was filed on June 27, 1988, under Title II of Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 USC 156(d)(2)(A).

C.E. Van Horn

Charles E. Van Horn
Deputy Solicitor
U.S. Patent and Trademark Office

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